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**MEDICAL MICROBIOLOGY BRANCH
VIROLOGY SECTION**

Specimen Requirements for Real-Time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) for Dengue Virus Serotypes 1-4 in Clinical Samples

Specimen Requirements for Real-Time (rti) Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) for Dengue Virus Serotypes 1-4 in Clinical Samples

Revised on September 15, 2017

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| Methodology: | CDC Dengue (DENV-1-4) Real-Time RT-PCR Assay |
| Performed: | The CDC DENV-1-4 Real-Time RT-PCR Assay is an FDA approved assay developed by the CDC for In-Vitro Diagnostic use (IVD). |
| Criteria for testing: | <p>Specimens meeting the case definition set by the Disease Investigation Branch (DIB) of the Disease Outbreak Control Division (DOCD) of the Department of Health. Approval by the DIB/DOCD, is <u>required</u> before specimens are tested.</p> <p>Clinical signs and symptoms compatible with Dengue fever.</p> |
| Turn-Around-Time: | Results are reported 2-3 business days after approval and receipt of specimen(s). |
| Specimen type required: | <p>Venous blood sample: Follow device manufacturer's instructions for proper serum or plasma collection and separation. Serum is the preferred specimen. The best type of tube is serum separator (tiger/speckled-top). Red-top (no additives) is also acceptable. For plasma specimens, use sodium citrate collection tube. Do not use heparin (green top) or EDTA (purple top).</p> <p>A minimum of 0.5 ml serum or plasma is required.</p> <p>Dengue specimens must be collected within the first eight (8) days from onset of signs and symptoms.</p> |
| Specimen storage / transport: | <p>Refrigerate serum or plasma at 4°C or maintain on ice for no longer than 24 hours. If storage/transport will exceed 24 hours, freeze serum or plasma at -20°C or lower.</p> <p>Ship separated serum or plasma on cold packs (i.e. 4°C) within 24 hours. Ship on dry ice if the specimens have been frozen at -20°C or lower.</p> |

Follow instructions for Class B - Biological Substance of the U.S. Department of Transportation (U.S. DOT) and International Air Transport Association (IATA) for packing and shipping.

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| Specimen submission: | Submitters: Clinical laboratories and the Disease Investigation Branch (DIB). Please notify DIB and the SLD Medical Microbiology Branch (MMB) prior to the submission of specimens. |
| Criteria for rejection: | <ul style="list-style-type: none">• Specimen is received in a container that is leaking;• Specimen is not collected in a proper container or special handling instruction is not followed;• Blood collected with heparin or EDTA tubes;• Specimen is not received at 4°C or packed in blue ice;• Frozen specimens not shipped in dry ice;• Specimen quantity is insufficient to perform the tests;• Unlabeled specimens;• Incomplete specimen labeling/documentation. |
| Stability: | Separated serum or plasma must be refrigerated at 2-8°C for no longer than 24 hours. If the specimen cannot be transported to the State Laboratories Division within 24 hours after collection and separation, it should be frozen at -20°C or lower. Frozen samples should be shipped in dry ice. |
| Requisition Form: | <p>Each specimen submitted must have a completed Form 81.3. Submitter is responsible for completing SLD Form 81.3 (including but not limited to the following information: patient identifier, date of onset of illness, signs and symptoms, travel history, immunization history, name and address of submitter).</p> <p>Requisition forms shall be placed in a separate bag and shall not be packed with the specimen(s).</p> |
| Normal Value: | No Dengue Virus Nucleic Acid Detected |
| Result Notification: | Laboratory results are reported to the submitters and Disease Investigation Branch (DIB) of the DOH Disease Outbreak Control Division (DOCD). Laboratory reports for the DIB will be posted to the DOCD SharePoint. |

Test performed at:

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State Laboratories Division
Department of Health
2725 Waimano Home Road, 2nd Floor
Pearl City, Hawaii 96782

Contact:

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Approved By:



A. Christian Whelen, Ph.D.
Administrator, State Laboratories Division

9/21/2017
Date